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STATE OF DELAWARE
BOARD OF PHARMACY

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| PUBLIC MEETING NOTICE: | BOARD OF PHARMACY |
| DATE AND TIME: | Wednesday, February 18, 2015 9:30 am |
| PLACE: | Conference Room A, 2 nd Floor Cannon Building 861 Silver Lake Blvd., Dover, DE 19904 |
| APPROVED: | March 18, 2015 |

MEMBERS PRESENT

Kenneth Sellers, Public Member, President
Susan Esposito, R.Ph., Professional Member, Vice President
Joli Martini, R.Ph., Professional Member
Bonnie Wallner, R.Ph., Professional Member
Tejal Patel, PharmD, Professional Member
Hooshang Shanehsaz, R.Ph., Professional Member
Julia Wheatley, Public Member
Jay Galloway, Public Member

MEMBERS ABSENT

Kimberly Robbins, R.Ph., Professional Member

DIVISION STAFF/DEPUTY ATTORNEY GENERAL PRESENT

David W. Dryden, R.Ph., J.D., Executive Secretary
Eileen Kelly, Deputy Attorney General
Christine Mast, Administrative Specialist III
Michelle McCreary, Pharmacist Compliance Officer

ALSO PRESENT

Nicholas Karalis
Joe Giorno
Emily Salter
Benjamin Hwang
Jaime Frink
Timothy Dillon
Suzanne Raab-Long
Ann Campagna
Robert J Mullen
Nancy Sawyer
Kevin Morgan
Maryanne Holzapfel
Sarah Cannon
Jill Spivey

CALL TO ORDER

Mr. Sellers called the meeting to order at 9:32 a.m.

REVIEW OF MINUTES

A motion was made by Ms. Esposito and seconded by Mr. Shanehsaz, to approve the meeting minutes for January 21, 2015 as amended. The motion unanimously carried.

PRESIDENT'S REPORT

Mr. Sellers reported that the following volunteered to be members of the "Prescription Safety Committee": Michelle McCreary (Chair), Tejal Patel, Kimberly Robbins, Susan Esposito, Joli Martini, Hooshang Shanehsaz.

UNFINISHED BUSINESS

Complaint Status

13-09-11 – Assigned to Hearing Officer
13-12-11 – Assigned to Hearing Officer
13-19-11 – Forwarded to Office of Attorney General
13-01-13 – Forwarded to Office of Attorney General
13-04-13 – Forwarded to Office of Attorney General
13-05-13 – Forwarded to Office of Attorney General
13-06-13 – Forwarded to Office of Attorney General
13-20-13 – Forwarded to Office of Attorney General
13-26-13 – Assigned to Hearing Officer
13-01-14 – Forwarded to Office of Attorney General
13-03-14 – Assigned
13-04-14 – Assigned
13-05-14 – Assigned
13-06-14 – Forwarded to Office of Attorney General
13-07-14 – Forwarded to Office of Attorney General
13-08-14 – Assigned
13-09-14 – Forwarded to Office of Attorney General
13-10-14 – Forwarded to Office of Attorney General
13-11-14 – Forwarded to Office of Attorney General
13-12-14 – Forwarded to Office of Attorney General
13-13-14 – Assigned
13-14-14 – Forwarded to Office of Attorney General
13-15-14 – Assigned
13-16-14 – Assigned
13-17-14 – Assigned

Deliberations on Proposed Changes to Regulations

The purpose of the deliberation is to adopt regulation amendments as published to Rule 5.1.14.3 and 14.1.1. The adopted regulations will be published in the register of regulations on March 1, 2015 and become effective March 11, 2015 if approved. There was no public or written comment received. A motion was made by Mr. Shanehsaz and seconded by Ms. Martini to approve the regulations as amended. The motion unanimously carried.

Re-Review of Proposal to Deny

None

** A motion was made by Ms. Esposito and seconded by Ms. Martini. To amend and move ahead in the agenda while Ms. Kelly; Deputy Attorney General for the Board prepared herself for the hearing. The motion unanimously carried.

Proposal to Deny Hearing @ 9:40 am

Glen Rock Medical Pharmacy – Ms. Kelly Deputy Attorney General for the Board explained the “Proposal to Deny” hearing process. She asked the Board members to introduce themselves for the record. Nick Corralas, President, and Stephen Sieden, Vice President, were present and representing Glen Rock Medical Pharmacy. Ms. Kelly notified the representatives of their right to have 20 days written notice of the hearing of which they agreed to waive. She also explained their right to be represented by counsel which they also waived. A motion was made by Ms. Esposito and seconded by Ms. Martini to table the application for additional and updated information. The motion unanimously carried.

Re-Review of Tabled Applications

None

Consent Agreement Report

The Board received a progress report from Mr. Anthony Franzosa. Due to the nature of the information received Mr. Sellers, President of the Board asked for guidance from Ms. Kelly, DAG, and then read the excerpts from the report to the Board. The report will be filed with Mr. Franzosa’s records. A motion was made by Ms. Wallner and seconded by Ms. Esposito to accept the progress report provided put into the record. The motion unanimously carried.

Review of Practitioner/Pharmacy Ownership

No Report

DEA Federal Rules for Disposal

No Report

Regulations Discussion: Provisions for Disciplinary Action

Ms. Kelly reported that after review of disciplinary provisions in the statute there are two very distinct differences with Pharmacy and Pharmacists regarding discipline. She suggested that the Board begin reviewing the statutes and the rules and regulations to clarify disparity in both. The Board agreed to review both and offer some suggestions during the April meeting.

Remote Pharmacy Operations

Mr. Alex Zarow, Director of Pharmacy Services at Bay Health, presented information to the Board regarding real time video with bar code technology, which would enable verification by a pharmacist of a technician’s dispensing of non-controlled substances and IV preparations in a hospital setting at another location. There were two examples of services mentioned: Dose Edge and Med Keeper currently being utilized in other states. Ms. Kelly was asked to review the Boards’ statute to see if this process can be supported in its current state or if there would need to be legislative changes to occur should the Board decide to approve this process. The Board requested to leave this item on the agenda for further discussion.

NEW BUSINESS

Mr. Sellers read into the record the following ratifications:

Pharmacist and Intern Licensure Approval Ratifications

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|-------------------------------|----------------------|
| Pharmacist: A1-0004716 | Amy Floerke Isaacs |
| A1-0004717 | Madhurima Agumamidi |
| A1-0004718 | Paul J Danielraj |
| A1-0004719 | Meyyappan Ramanathan |
| A1-0004720 | Deanna Marie Rowe |
| A1-0004721 | Lakshmi Veerareddy |
| A1-0004722 | Abby Gayle Horseman |
| A1-0004723 | Kristina M. Riley |

A motion was made by Ms. Esposito and seconded by Ms. Patel to approve the ratification of the Pharmacist applications. The motion unanimously carried.

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|--------------------------------------|--------------------|
| Pharmacist Intern: A7-0002382 | Marco Lombardo |
| A7-0002383 | Jessica Lynn Olsen |

A7-0002384 Katie Elizabeth Andrews

A motion was made by Ms. Esposito and seconded by Ms. Patel to approve the ratification of the Pharmacist Intern applications. The motion unanimously carried.

Non-Resident Pharmacy Licensure Approval Ratifications

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|------------|----------------------------------|
| A9-0001574 | Hallandale Pharmacy |
| A9-0001575 | CareKinesis, Inc. |
| A9-0001576 | CareKinesis, Inc. |
| A9-0001577 | Biocure LLC |
| A9-0001578 | Promptcare Home Infusion LLC |
| A9-0001579 | Village Drug & Compounding, Inc. |
| A9-0001580 | Trucare Pharmacy |
| A9-0001581 | Brand Direct Health, LLC |
| A9-0001582 | Delmarva Pharmacy |
| A9-0001583 | Family Pharmacy |
| A9-0001584 | Kemet Care Compounding, LLC |
| A9-0001585 | Main Line Spine Pharmacy |
| A9-0001586 | Quality RX |
| A9-0001587 | Downing Labs, LLC |
| A9-0001588 | Coastal Drug |
| A9-0001589 | Independence Holding Company LLC |
| A9-0001590 | Medvantx Specialty Pharmacy |
| A9-0001591 | Woods Pharmacy, LLC |
| A9-0001592 | Medpoint Healthcare, LLC |

A motion was made by Mr. Galloway and seconded by Ms. Patel to approve the ratification of the Non-Resident Pharmacy applications. The motion unanimously carried.

Wholesale Distributor Licensure Approval Ratifications

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|------------|---------------------------------|
| A4-0001770 | Sigma-Aldrich Inc. |
| A4-0001982 | RemedyRepack Inc. |
| A4-0002160 | Atlantic Biologicals Corp. |
| A4-0002163 | DSC Logistics, Inc. |
| A4-0002164 | Exel Inc. |
| A4-0002165 | DPT Lakewood, LLC |
| A4-0002166 | McKesson Medical-Surgical, Inc. |
| A4-0002167 | Blenheim Pharmacal, Inc. |
| A4-0002168 | H.D. Smith, LLC |
| A4-0002169 | Huvepharma, Inc. |

A motion was made by Mr. Galloway and seconded by Ms. Patel to approve the ratification of the Wholesale Distributor applications. The motion unanimously carried.

Medical Gas Dispensers

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|------------|-----------------------------------|
| A2-0000116 | Nettie D LLC dba BP Gamma Medical |
| A2-0000117 | Comfort Sleep Services |
| A2-0000118 | Ion of Bergen |

A motion was made by Mr. Galloway and seconded by Ms. Patel to approve the ratification of the Medical Gas Dispensers applications. The motion unanimously carried.

Retail Pharmacy Licensure Approval Ratification

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|------------|---------------------|
| A3-0000980 | Meds Your Way, Inc. |
|------------|---------------------|

A motion was made by Mr. Galloway and seconded by Ms. Patel to approve the ratification of the Retail Pharmacy applications. The motion unanimously carried.

Retail Pharmacy Temporary Licensure Approval Ratification

None

Outsourcing Facility

None

Pharmacist-In-Charge Interviews

Ms. Esposito conducted a PIC interviews with:

Robert Mullin, Nemours Alfred I DuPont Hosp. for Children Wilmington, De

Consultant Pharmacist Interviews

Ms. Esposito conducted Pharmacist Consultant interviews with:

Emily W Salter, Manor House Nursing Home Seaford, De

Benjamin Hwang, Delaware Hospital for Chronically Ill. Smyrna, DE

Board Review and Consideration of Lifting of Suspension

LaToya Kennedy sent a written request to lift her suspension as required by the consent agreement. Ms. Kennedy also requested that the Board review her discipline as she felt it was an error. She requested that the discipline be expunged from her record. The Board reviewed the letter of request and deliberated briefly, a motion was made by Mr. Shanehsaz and seconded by Ms. Wallner to lift the suspension and to deny the request for expungement. The motion unanimously carried.

Review of Applications by DAG

Pharmacy Board DAG Eileen Kelly provided guidance on the following disciplinary actions for applications received followed by the Board ruling:

Facility: Stoney Creek Pharmacy, a motion was made by Ms. Wallner and seconded by Mr. Galloway to approve the application, Ms. Martini and Mr. Shanehsaz opposed. The motion carried.

Facility: Huemonetics Corporation, a motion was made by Ms. Martini seconded by Ms. Esposito, to approve the application. The motion unanimously carried.

Facility: Leiter's Compounding, a motion was made by Ms. Martini and seconded by Ms. Esposito, to table the application. The motion unanimously carried.

Facility: Sterile Compounding Pharmacy, a motion was made by Ms. Wallner and seconded by Ms. Esposito, to approve the application. The motion unanimously carried.

Facility: Midwest Veterinary Supply, a motion was made by Ms. Martini and seconded by Ms. Wallner, to approve the application. The motion unanimously carried.

Review of Hearing Officer Recommendation

None

Review of Crimes Listing For Discussion

No Report

Review of CE Received

None

COMMITTEE REPORTS

Legislative – Joli Martini, Jay Galloway, Kim Robbins, Tejal Patel and David Dryden

Mr. Dryden announced legislation that was put in place to exclude Veterinarians and Methadone Clinics from the 72 hour dispensing limitation.

Continuing Education – Joli Martini, Bonnie Wallner, Tejal Patel and David Dryden:

None

Consumer Affairs – Ken Sellers, Jay Galloway and Julia Wheatley

No Report

Professional Liaisons – Kim Robbins and Tejal Patel:

None

Controlled Substance Liaisons – Kenneth Sellers, Tejal Patel, Jay Galloway and David Dryden:

None

Prescription Safety Committee – Michelle McCreary (Chair), Kenneth Sellers, Tejal Patel, Kimberly Robbins, Susan Esposito, Joli Martini, Hooshang Shanehsaz

Mr. Sellers announced the committee members that are listed above and appointed Ms. McCreary as the Chair for the Committee. She will announce at the next meeting a tentative schedule of meetings for the committee.

COMMITTEE UPDATES REGARDING PROPOSED REGULATIONS

USP 795 & 797 Committee – Tejal Patel, Brenda Pavlic, Hooshang Shanehsaz, Calvin Freedman and David Dryden:

Mr. Dryden reported that the proposed regulations are completed and ready to be presented during a hearing. The hearing will be tentatively scheduled for April 15, 2015 during the regularly scheduled meeting.

Pharmacy Technician Licensure Committee – Kim Robbins, Tejal Patel, Kevin Musto, Maryanne Holzapfel, Anne Pyle, Susan Esposito and David Dryden:

There is a meeting immediately following this meeting.

Collaborative Care Committee – Bonnie Wallner, Cheri Briggs, Cheryl Heiks, Drew Wilson, Deborah Hamilton, Joli Martini, Julie Miro-Wenger, Mark Thompson, Mike Perza, Nick Biasotto, Pooja Dogra, Tejal Patel, Terri Corbo, William Harbester, David Dryden:

Ms. Julie Miro-Wenger reported that they have not met in the previous four or five months due to other legislative priorities. They have put language forward to the Medical Society for review during their January 2014 meeting. They came back with two questions. The committee addressed those two questions and presented them during their February 2014 meeting. During the February meeting the Medical Society had many more questions that will need to be addressed before moving forward. The committee is focused on getting the support of the Medical Society before moving further in the project.

BOARD CORRESPONDENCE

Mr. Dryden provided the following handouts for the Board to review:

Yahoo News Article - Zogenix gets Approval for New Version of Painkiller Zohydro,

Anonymous Letter Received – Related to Pharmacist Breaks,

NABP – Rogue Internet Drug Seller Activity Highlights Need for .Pharmacy Domain Public Health Initiative*

EXECUTIVE SECRETARY, INSPECTION & PMP REPORT - David Dryden, Michelle McCreary, Samantha Nettesheim

Mr. Dryden spoke about an alert he sent on behalf of Medicaid regarding Medicaid Pharmacy Providers. He also informed the Board that 2 members of the Board as well as himself will be attending meetings in March and will not be attending the March meeting. Mr. Dryden spoke about the Office of Controlled Substances new 1 CE required course needed for renewal. The course from the Medical Society is almost completed with oversight from the division office. Ultimately, the division completed their own CE project to provide a means of completing the CE at no charge. The Medical Society also has a CE program for a fee. The Division staff has been fielding numerous calls for direction in completing the course.

Samantha Nettesheim is continuing her work with the University of Delaware contracts for the PMP project.

Ms. Michelle McCreary, Pharmacy Compliance Officer provided the Board an update of activities. She has completed 10 routine inspections, 1 remodel inspection, 1 new opening inspection, assisted with the CMS Validation Survey and provided support to the Investigative Unit with Pharmacy complaints as needed.

NEWSLETTER UPDATES

No Report

OTHER BUSINESS BEFORE THE BOARD

Legality of Pharmacies Providing Kickbacks to Prescribers in Exchange for Referrals from Colorado; the Board requested to keep as an agenda item under Practitioner/Pharmacy Ownership for future discussion.

Mr. Dryden shared with the Board upcoming meetings in March: FDA meeting to be attended by Mr. Dryden and Hooshang Shanehsaz; MPJE Meetings to be attended by Michelle McCreary and Tejal Patel.

PUBLIC COMMENT

Mr. Chris Lidow addressed the Board regarding the anonymous letter received about getting proper breaks for pharmacists. He stated he is not a pharmacist but, in fact knows the identity of the author of the letter and several other pharmacists as well. His belief is after not providing proper breaks to pharmacists it is a public health issue. Pharmacists are routinely scheduled for 12 hour shifts. This creates room for error due to exhaustion. His belief is that this is not only a business issue or department of labor issue but also a public health issue. He feels that this should be addressed by the Pharmacy Board in some manner to protect the public. He stated that he has reviewed other states statutory and regulatory laws. There are several states that have added or ammended statute and/or regulatory changes to address this issue and there are several others considering it.

NEXT SCHEDULED MEETING

The next meeting is scheduled for March 18, 2015 at 9:30 Am., Conference Room A 2nd floor.

ADJOURNMENT

There being no other business before the Board a motion to adjourn the meeting was made by Ms. Esposito, seconded by Mr. Galloway at 12:17 pm.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Mast", written in a cursive style.

Christine Mast
Administrative Specialist III
Liaison, Board of Pharmacy